

**Pentacel® Vaccine Now Available to All Providers in Massachusetts**  
**-- Please Order Now to Prevent Hib Shortage from Getting Worse --**

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### Background

Since December 2007, there has been a national shortage of Hib vaccine. The Centers for Disease Control and Prevention (CDC) has been making a monthly allocation of Hib vaccine to all states

In July the CDC announced that every state would be **required** to use some doses of Pentacel® to help diminish the impact of the ongoing national Hib shortage. The Massachusetts Department of Public Health (MDPH) is now receiving a portion of our Hib vaccine allocation as Pentacel®. The remainder of our allocation will be single antigen ActHib® vaccine. In August 2008, The Massachusetts Chapter of the American Academy of Pediatrics' (MCAAP) Committee on Vaccine Purchasing Strategies initially endorsed, by emergency vote, an interim plan to make Pentacel® vaccine available to some providers.

- On September 15, 2008, the committee met and approved **expansion** of Pentacel® availability to **all** providers in the state.
- MDPH urges **all** providers to please **consider** ordering Pentacel® to preserve our state's Hib supply to maintain the 3-dose infant Hib schedule -- and avoid having to go to a 1-2 dose Hib infant schedule (as has happened in other states).
- If some providers don't order Pentacel® **immediately**, MA's Hib supply may be **depleted** after the first 2 weeks of the month. Then MDPH will have to assign Pentacel® to some practices as part of their Hib allocation.

Providers who wish to continue to use Pediarix™ can continue to do so, for the time being. However, please be aware that continued use of this vaccine may exacerbate the Hib shortage in our state. The committee will re-examine policies surrounding Pediarix™ in a year's time, after the Hib shortage has resolved, and there is enough experience with Pentacel® to know if the supply of this vaccine can meet the demand.

### Pentacel® Vaccine Recommendations

On June 23, 2008 Pentacel®, a combination diphtheria, tetanus, pertussis, polio and Hib (DTaP-IPV/Hib) vaccine, was licensed by the Food and Drug Administration (FDA) for use in children 6 weeks through 4 years of age for routine immunization with 0.5mL at 2, 4, 6 and 15-18 months of age.

Pentacel® is supplied as single-dose vials, 5 doses to a package. A single-dose vial of liquid DTaP-IPV vaccine is used to reconstitute a single dose vial of lyophilized Hib (ActHib®).

This vaccine must be kept at refrigerator temperature (35°-46° F or 2°-8°C). It must never be frozen. Vaccine exposed to freezing temperature must not be used.

You will need to record the lot number from the Hib component **and** the lot number for the DTaP-IPV component.



**Contraindications and Precautions.** Contraindications and precautions for Pentacel® are the same as those for DTaP, IPV, and Hib vaccines. Pentacel® may be used whenever any component(s) of the combination is indicated and no other component of the vaccine is contraindicated. This means that Pentacel® can be used when a child needs one or two components, but does not need the others.

**DTaP Considerations:** The 4th dose of DTaP-IPV/Hib may be given as early as 12 months of age if the clinician feels an opportunity to vaccinate may be missed later and if six months has elapsed since the 3rd dose of DTaP-IPV/Hib. Whenever feasible, the same manufacturer's DTaP product should be used for the primary series but that vaccination should not be deferred if the specific DTaP vaccine brand previously administered is unavailable or unknown.

**Polio Considerations.** DTaP-IPV/Hib given at 2, 4, 6, 12-18 months would provide 4 valid doses of IPV, when an accelerated schedule is needed, if the minimum age and interval requirements are met. CDC is reviewing whether or not this would constitute an adequate polio schedule on a routine basis.

**Hib Considerations.** The Hib component in Pentacel® is ActHib (Hib-TT). Certain American Indian/Alaskan Native (AI/AN) children are at increased risk for Hib disease, particularly in the first 6 months of life. Failure to use polyribosylribitol phosphate-meningococcal outer membrane protein (PRP-OMP)-containing Hib vaccine preparations for the first dose has been associated with excess cases of Hib disease in AI/AN infants living in communities where Hib transmission is ongoing and exposure to colonized persons is likely. It may be prudent for clinics that serve predominantly AI/AN children to use only PRP-OMP-containing Hib vaccines (e.g. Merck's PedvaxHIB®) and not Pentacel® or ActHib®. If you are a provider in Massachusetts to whom this applies, please contact the MDPH vaccine unit to arrange to get some doses of PRP-OMP Hib vaccine.

**Minimum Age and Interval Tables.** The following *minimum* ages and intervals are defined for the component vaccines in various Advisory Committee on Immunization Practices (ACIP) statements, and in particular in Table 1 on page 3 of the 2006 version of the General Recommendations on Immunization (<http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf>) and on pages 31-32 of the 2006 AAP Red Book. The *maximum* age is in accordance with licensure.

Parameter	Age/interval
Minimum age for any dose	6 weeks
Minimum interval for doses 1 and 2	4 weeks
Minimum age for dose 2	10 weeks
Minimum interval for doses 2 and 3	4 weeks
Minimum age for dose 3	14 weeks
Minimum interval for dose 3 and 4	<b>6 months</b> (determined by DTaP component; minimum interval for dose 3-4 is 2 months for Hib and 4 weeks for IPV)
Minimum age for dose 4	<b>12 months</b> (determined by DTaP and Hib components). Note that both the minimum interval AND age must be met for the fourth dose of DTaP or Hib (as Pentacel® or any other formulation) to be counted as valid
Maximum age for <b>any</b> dose	4 years, 364 days (i.e., do not administer at age 5 years or older)*

\* Doses inadvertently administered to those  $\geq 5$  years of age do not have to be repeated.

Please refer to *Suggested Schedules Integrating Pentacel® and/or Pediarix™ into the Hep B, Hib, DTaP, IPV Series* (attachment 1) for guidance on schedules for Pentacel®, Pediarix™ and the single antigen series for Hep B, Hib DTaP and IPV during this time of Hib vaccine shortage.

CDC has developed guidance about Pentacel®. It can be found at <http://www.cdc.gov/vaccines> and it will also be included in all boxes shipped from the national distributor (McKesson). The ACIP will publish its official recommendations about Pentacel®, as a Notice to Readers in the Morbidity and Mortality Weekly Report (MMWR) (Available at: <http://www.cdc.gov/mmwr/>). MDPH documents related to Pentacel® can be found at <http://www.mass.gov/dph/imm>.

## **No Change in National Policy for Deferring the 4th Dose of Hib Vaccine**

The availability of Pentacel® will improve the Hib vaccine supply situation in the United States. However, it will **not** be sufficient to reinstate the 4th dose of the Hib vaccine for healthy children at 12-15 months of age (except for high risk children who should continue to receive the 4<sup>th</sup> dose.)

Although Pentacel® is approved by FDA for the 4<sup>th</sup> dose in the DTaP, IPV and Hib series, providers should **not** use it for this purpose until there is further improvement in the Hib vaccine supply (anticipated for late 2008 or early 2009).

**Until the Hib supply improves, Pentacel® should ONLY be used for the first 3 doses of the DTaP, IPV and Hib vaccination series.** When seeing healthy children 15-18 months of age, use DTaP vaccine for the 4<sup>th</sup> dose of that series.

## **MDPH Recommendations for Introduction of Pentacel® Into a Practice**

For practices using only single-antigen vaccines, transition to Pentacel® is relatively straightforward. These practices could begin using Pentacel® as the first dose in the primary series for their two-month olds. Infants already started on single-antigen vaccines can finish the series with separately administered DTaP, IPV, and Hib vaccines. An alternative is to switch all infants to Pentacel®. Please refer to Table 3 in *Suggested Schedules Integrating Pentacel® and/or Pediarix™ into the Hep B, Hib, DTaP, IPV Series* (attachment 1).

For practices using Pediarix™ (DTaP-IPV-HepB), the introduction of Pentacel® (DTaP-IPV/Hib) requires a little more planning. Confusion and administration errors may result when both Pediarix™ and Pentacel® are in use simultaneously in the same practice. These two combination vaccines are overlapping in the DTaP and IPV antigens – but, Pediarix™ contains HepB and not Hib; and Pentacel® contains Hib and not HepB. For practices incorporating Pentacel®, it is easiest to begin with administration of Pentacel® to their newborns, while infants already started on Pediarix™ could finish the series with Pentacel®, single antigen vaccines or by using up your Pediarix™ inventory. Please refer to *Suggested Schedules Integrating Pentacel® and/or Pediarix™ into the Hep B, Hib, DTaP, IPV Series* for several different options (attachment 1).

Inventory management will be challenging in practices that have both Pediarix™ and Pentacel®, and may result in vaccine wastage if inventories are not monitored closely. The risk of children missing a dose of hepatitis B or Hib vaccine **increases** when both products are available. In order to **decrease** the chances for over immunization, underimmunization and medical errors, MDPH recommends:

- practices who receive Pentacel®, **not** order **any** more doses of Pediarix™ (DTaP-IPV-Hep B);
- if you feel you need a transitional inventory of Pediarix™ for those children who started the schedule on Pediarix™, plan on no more than 4-months of overlapping inventories. In addition, be aware that continued use of Pediarix™ could **exacerbate** the Hib shortage in MA.

**Helpful Hint:** While using up your Pediarix™ inventory, try to be aware of the different presentations of Pediarix™ and Pentacel®.

- Pediarix™ comes in liquid form in single dose vials that do not have to be reconstituted.
- Pentacel® requires reconstitution.

## Guidelines for Pentacel® Ordering and Inventory Management

This guidance is designed to minimize vaccine inventory losses, overimmunization, underimmunization and to support provider practices in the implementation of this new vaccine.

**Note: MDPH recommends providers using Pentacel® stop ordering Pediarix™, in order to minimize potential medical errors and minimize vaccine wastage.**

Vaccine	Order and Inventory Management Guidelines
Hib (ActHIB®)	<ul style="list-style-type: none"><li>Place all ActHIB® vaccine in front of Pentacel® in the refrigerator to ensure the single antigen inventory is depleted before Pentacel® is administered.</li><li>A minimal amount of ActHIB® may be kept on hand to meet patients needing single antigen Hib vaccine.</li></ul>
IPV (IPOL®)	<ul style="list-style-type: none"><li>Providers who have been using Pediarix™ will not need to change their ordering pattern for IPV vaccine when switching to Pentacel®.</li><li>Those previously using only single antigen IPV, will need to decrease the number of doses ordered when switching to Pentacel®.</li></ul>
Hepatitis B (Recombivax®)	<ul style="list-style-type: none"><li>Providers who have been using Pediarix™ will need to increase the order volume of Hep B vaccine to meet the primary series need for hepatitis B vaccination once they begin using Pentacel®.</li><li>Providers using only single antigen Hep B vaccine will not have their order pattern affected when switching to Pentacel®.</li></ul>
DTaP/IPV/Hep B Combination (Pediarix™)	<ul style="list-style-type: none"><li>MDPH recommends existing inventories of Pediarix™ should be <b>depleted</b> as soon as possible after initiating the use of Pentacel®.*</li></ul>

\* If needed, a 4-month transitional inventory of Pediarix™ can be requested. But, MDPH is concerned that this may result in medical errors and significant inventory losses, as doses of Pediarix™ expire (\$48.75 per dose). This vaccine wastage could have a serious impact on the budget for state-supplied vaccines. In addition, continued use of Pediarix™ could exacerbate the Hib vaccine shortage in MA.

MDPH's *Vaccine Order Form*, *Vaccine Usage Aggregate Report* and the *Vaccine Administration Record*, dated August 2008, have been modified to include Pentacel®. These documents and other MDPH guidance are available at [www.mass.gov/dph/imm](http://www.mass.gov/dph/imm); then click on 'vaccine management'.

### If you wish to order Pentacel®:

- Please download the new *Vaccine Order Form*, *Vaccine Usage Aggregate Report* and the *Vaccine Administration Record* from the MDPH website (above).
- Complete and fax your *Vaccine Order Form*, *Vaccine Usage Aggregate Report* and your temperature logs to MDPH at 617-983-6924.

If you have any questions about ordering and accountability or would like specific guidance on how best to adjust your orders, please contact the MDPH Vaccine Management Unit (617-983-6828).

### Vaccine Information Statements (VISs)

When using combination vaccines, please remember that you need to provide either the VISs for the individual antigens or the Multiple Vaccines VIS (check off the vaccines given: hepatitis B, polio, pneumococcal disease, DTaP, rotavirus and Hib). The most current VISs are available at [www.cdc.gov/vaccines/pubs/vis/](http://www.cdc.gov/vaccines/pubs/vis/).

We will keep you informed of any changes in Pentacel® and Hib availability. All questions about Pentacel® can be addressed to the main number for the Immunization Program at 617-983-6800.

Massachusetts Department of Public Health (MDPH)  
Immunization Program

### Suggested Schedules Integrating Pentacel® and/or Pediarix™ into the Hep B, Hib, DTaP, IPV Series -- During the Hib Shortage Period\*

Whether providers are currently using Pediarix™ or single antigen vaccines -- when making decisions regarding the integration of Pentacel® into their practices it is important to remember:

- Pediarix™ contains DTaP, IPV and Hep B
- Pentacel® contains DTaP, IPV and Hib

The tables below provide guidance on suggested schedules for the integration of Pentacel® into practices using Pediarix™ and the single antigen series for Hep B, Hib, IPV, DTaP vaccines for healthy children\* during the Hib vaccine shortage. (Remember, during the shortage a 3-dose Hib series is recommended for all healthy children. High-risk children should continue to receive 4 doses.)

- **Using Pediarix™ for the 1<sup>st</sup> and 2<sup>nd</sup> Dose.** Table 1 outlines how to introduce Pentacel® in your practice using Pediarix™ for the 1<sup>st</sup> dose only, and Table 2 outlines how to introduce it using Pediarix™ for both the 1<sup>st</sup> and 2<sup>nd</sup> doses in the series. With these schedules, Pentacel® and single antigen vaccines are used for the remaining doses.
- **Using Pentacel for All Doses.** Table 3 is a schedule using Pentacel® for all doses.
- **Using Pentacel® for the 1<sup>st</sup> and 2<sup>nd</sup> Doses.** Table 4 outlines how to introduce Pentacel® into your practice using it for the 1st dose only, and Table 5 using Pentacel® for the 2<sup>nd</sup> dose only in the series. With these schedules, Pediarix™ and single antigen vaccines are used for the remaining doses.
- **Using No Pentacel®.** Tables 6 and 7 outline possible schedules for Hep B, Hib, DTaP and IPV without any Pentacel®, but using Pediarix™ and single antigen vaccines for some doses.

**Table 1. Schedule for Hep B, Hib\*, IPV, and DTaP Using Pediarix™ for First Dose and Pentacel® for Remainder of Doses**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B			Hep B		
	Hib				
				DTaP	DTaP
					IPV
		Pentacel®	Pentacel®		
	Pediarix™				

**Table 2. Schedule for Hep B, Hib\*, IPV, and DTaP Using Pediarix™ for First and Second Doses and Pentacel® for Third Dose**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B			Hep B		
	Hib	Hib			
				DTaP	DTaP
					IPV
			Pentacel®		
	Pediarix™	Pediarix™			

**Table 3. Schedule for Hep B, Hib\*, IPV, and DTaP Using Pentacel® for All Doses**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B		Hep B		
				DTaP	DTaP
					IPV
	Pentacel®	Pentacel®	Pentacel®		

**Table 4. Schedule for Hep B, Hib\*, IPV, and DTaP Using Pentacel® For First Dose Only and Pediarix™ for Remainder of Doses**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B				
		Hib	Hib		
				DTaP	DTaP
					IPV
	Pentacel®				
		Pediarix™	Pediarix™		

**Table 5. Schedule for Hep B, Hib\*, IPV, and DTaP Using Pentacel® For Second Dose Only and Pediarix™ for First and Third Doses**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B					
	Hib		Hib		
				DTaP	DTaP
					IPV
		Pentacel®			
	Pediarix™		Pediarix™		

**Table 6. Schedule for Hep B, Hib\*, DTaP and IPV without Pentacel® or Pediarix™**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B	Hep B		Hep B		
	Hib	Hib	Hib		
	DTaP	DTaP	DTaP	DTaP	DTaP
	IPV	IPV	IPV		IPV

**Table 7. Schedule for Hep B, Hib\*, IPV, and DTaP Using Pediarix™ Only (No Pentacel®)**

Birth	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B					
	Hib	Hib	Hib		
				DTaP	DTaP
					IPV
	Pediarix™	Pediarix™	Pediarix™		

Pentacel® contains DTaP, IPV and Hib

Pediarix™ contains DTaP, IPV, and Hep B

Neither Pentacel® nor Pediarix™ can be used prior to 6 weeks of age.

In general ACIP recommends the same brand of DTaP be used for all doses of the series. However, different brands can be used if providers do not know or have available the brand of DTaP used for prior doses.

\*When supplies are sufficient an additional dose of Hib vaccine (single antigen or as part of a combination vaccine) is recommended for healthy children at 12-15 months of age (at least 2 months after the prior dose). **Either Pentacel® or single antigen Hib vaccine may be used at 12-15 months for children who are at increased risk of Hib disease or who have not completed a complete primary Hib schedule. If Pentacel® is administered at 12-15 months of age a dose of DTaP at 15-18 months is not needed. See MMWR 2007;56(No.50):1318-1320 for additional details.**

The Advisory Committee on Immunization Practices (ACIP) will publish its official recommendations about Pentacel®, as a Notice to Readers in the Morbidity and Mortality Weekly Report (MMWR) (Available at: <http://www.cdc.gov/mmwr/>).

We will keep you informed of any changes in Pentacel® and Hib availability. If you have any questions about Pentacel®, please do not hesitate to contact the MDPH Immunization Program number at 617-983-6800.